

The Honorable Kiyo A Matsumoto  
United States District Court  
Eastern District of New York  
225 Cadman Plaza East  
Brooklyn, NY 11201

August 17, 2009

Re: Costoso v Amgen et. Al.  
Case # 09-3337(KAM)

Dear Judge Matsumoto;

I am the attorney for Plaintiff's, and in accordance with your order dated August 12, 2008, I am replying the Defendant's attorney's pre motion letter of August 7, 2009.

Since this proposed motion is made to dismiss the complaint under Federal Rules 8, the only issue at this time is whether plaintiff's complaint complies with the requirement of being a "...short and plain statement of the claim showing that the pleader is entitled to relief" See Federal Rule 8. In addition the complaint must comply with the added requirements of Federal Rule 9(b) and 12 (b)(6) of particularity as to those causes of action alleging fraud. No technical form of pleading is required, and pleadings are to be liberally construed to do substantial justice.

Plaintiff, Ellen Costoso, was prescribed the drug Enbrel for treatment of her rheumatoid arthritis in the year 2005. In the fall of 2007, she became extremely ill, requiring hospitalizations on two separate occasions. At the time of her second hospitalization, it was discovered by the treating doctors that there was a direct link between her intake of Enbrel and her deteriorating physical condition. It is specifically stated in her voluminous medical records and neurology reports that Plaintiff's injuries are secondary to her enbrel intake. Accordingly, Plaintiff's claim against the Defendants is not speculative but is based on a direct link between the medication and her injury.

Under New York law, a drug manufacturer, like any other manufacturer, can be held liable for a defective product under various legal theories and causes of action. See Lindsay v Ortho Pharmaceutical Corp., 637 F.2<sup>nd</sup> 87.

Based on the above facts, a complaint was prepared which is broken down into 8 separate causes of action. The complaint fulfills its primary function of advising Defendants of the nature of Plaintiff's claims so that they can interpose an answer to those claims.

As to a recitation of injuries, most attorneys do not set forth a detailed itemization of injuries in a complaint, but do provide a complete and thorough statement of injuries in a bill of particulars. Under the standard of Rule 8, the statement that Plaintiff suffered 'severe, serious and permanent personal injuries ' (complaint at paragraph 24) is sufficient for pleading purposes.

As to the cause of action seeking punitive damages, the issue of Defendants "exceptional misconduct", or lack thereof, cannot be litigated in a Rule 8 sufficiency motion. However, for pleading purposes, it does set forth a valid cause of action in a simple and direct manner.

The issue of whether the Enbrel warnings are adequate or not, exceeds the issue of whether the complaint is sufficient under Rule 8, and is an issue which will likely be raised at another time in a motion for summary judgment. However, it must be noted that Defendant's attorney's 'opinion' as to the sufficiency of the warnings is not determinative. In addition, as noted earlier, a full recitation of Plaintiff's injuries are not even set forth in the complaint. Therefore, how can Defendant's attorney draw any rational or valid conclusion at this time as to the adequacy of those warnings? In any event, it will be a disputed issue of fact whether the Defendant's warnings were adequate, accurate, clear and consistent and whether the warning was of sufficient intensity to the risks associated to the taking of the drug. See Golod v LaRoche, 964 F. Supp. 841.

After the court examines Plaintiff's complaint, I believe that it is in full compliance with Federal Rules 8, 9 and 12as being a simple and concise statement with sufficient particularity. Should the court find any cause of action to be insufficient, it will be requested that the Plaintiff be given leave to replead and amend that portion of the complaint. Thank you for your kind consideration of this matter.

Very truly yours,

RONALD SAFFNER